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10/737,314	12/16/2003	Yogesh B. Gianchandani	30275/2419	5950

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/737,314

Applicant(s)

GIANCHANDANI ET AL.

Examiner

DIANE YABUT

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This action is in response to applicant's amendment received on 09/18/2009.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 8-16, 36-39, 41-44, 48-49 are rejected under 35 U.S.C. 102(a) as being anticipated by **Leopold et al.** (U.S. Pub. No. **2002/0173839**).

Claims 1-3, 6, 8-16, 36-39, 41-44, 48-49: Leopold et al. disclose a planar structure expandable into a 3-D structure or tubular stent, the planar structure comprising first and second spaced side beams or hinges **126** on opposing sides of the planar structure which extend continuously along a longitudinal axis, and a plurality of spaced cross-bands or folded/looped beams which connect the side beams together wherein a first set of the cross-bands **122** are expandable in a first direction substantially perpendicular to the longitudinal axis to form a 3-D structure and wherein a second set of the cross-bands **124** are expandable in a second direction substantially opposite the first direction to form a mesh-like 3-D structure (Figures 19-21; paragraphs 72-76). The folded beams have an involute or curved pattern and switchback or alternating pattern. The stent may

be coated with a biocompatible surface coating and is made of a biocompatible material or shape-memory alloy (paragraph 65).

3. Claims 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by **Fischell et al.** (U.S. Patent No. **6,086,604**).

Claims 46-47: Fischell et al. disclose a unitary stent structure disposed in a plane when in a non-expanded or non-deployed position and having a longitudinal axis, first **4T** and second **4B** parallel spaced apart side beams which extend parallel along the longitudinal axis, and a plurality of spaced cross-bands including a series of folded beams having an involute or switchback pattern which connect the side beams together wherein a first set of the cross-bands **2'''** are expandable in a first direction substantially perpendicular to the longitudinal axis to form a 3-D structure (Figures 6-9). A second set of the cross-bands **2'''** are expandable in a second direction substantially opposite the first-direction to form a mesh-like tubular 3-D structure and each of the cross-bands include hinges (**4R** and **4L**) for interconnecting adjacent folding beams and allowing folded back beam sections to rotate relative to one another about a rotation axis (from Figure 4 to Figures 6-7).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**).

Claims 4-5: Leopold et al. do not expressly disclose the stent plastically deforming during expansion in order to be free-standing. However, this would depend on the material of the stent, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plastically deformable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Plastically deformable materials are also well known in the art for deploying stents.

6. Claims 7, 17, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Smith et al.** (U.S. Pub. No. **2002/0156525**).

Claims 7, 17, and 40: Leopold et al. disclose the claimed device except for the planar structure including a conductive foil and the sheet material including conductive foil, and wherein side beams and cross-bands are formed by electric discharge machining the conductive foil, and wherein a longest beam section of the plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis.

Smith et al. teach a conductive foil and the sheet material including conductive foil, and wherein side beams and cross-bands are effectively formed by electric discharge machining the conductive foil (paragraph 33). It would have been obvious to

one of ordinary skill in the art at the time of invention to provide conductive foil and forming the cross-bands by electric discharge machining, as taught by Smith et al., to Leopold et al. in order to form the stent "faster and with higher quality." Smith et al. also teach a longest beam section **100** of the plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis (Figures 1-2b). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the cross-bands of Leopold et al. to a plurality of interconnected and folded back first and second beam sections extends parallel to the longitudinal axis, as taught by Smith et al., in order to enhance the kink resistance and flexibility of the cross-bands (paragraph 29).

7. Claims 18-23, 25, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Pacetti** (U.S. Pub. No. **20020188345**).

Claims 18-23, 25, and 45: Leopold et al. disclose the claimed invention, including the 3-D structure comprising a helical coil including first and second spaced rings at opposite ends thereof and wherein each of the rings is formed by an adjacent pair of expanded crossbands (hinges **126** may be on both sides of the stent to form rings and a helical coil, paragraph 73), except for at least the first side beam including a link portion being thinned or being made of a fragile material relative to the other portions of the first side beam having a mechanical strength lower than other portions of the first side beam

to allow the first side beam to break at the link portion during expansion of the first set of cross-bands, the structure comprising at least one electrical inductor.

Pacetti teaches at least a first side beam including a link portion being thinned or being made of a fragile material relative to the other portions of the first side beam having a mechanical strength lower than other portions of the first side beam to allow the first side beam to break at the link portion during expansion of the first set of cross-bands, the structure comprising at least one electrical inductor (paragraphs 23 and 36). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a weak link portion, as taught by Pacetti, to Leopold et al. in order to facilitate imaging the stent with MRI.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Pacetti** (U.S. Pub. No. **2002/0188345**), as applied to claim 23 above, and further in view of **Da Silva et al.** (U.S. Patent No. **6,729,336**).

Claim 24: Leopold et al. disclose the claimed device including a first ring and side beams and cross-bands, except for the elements including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure.

Da Silva et al. teach a stent including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure in order to enhance a signal (col. 7, lines 7-24). It would have been obvious to one of ordinary skill in the art

at the time of invention to provide a dielectric part which also insulates, as taught by Da Silva et al., to Leopold et al. in order to better enhance a signal.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Leopold et al.** (U.S. Pub. No. **2002/0173839**) in view of **Da Silva et al.** (U.S. Patent No. **6,729,336**).

Claim 24: Leopold et al. disclose the claimed invention including a first ring and side beams and cross-bands, except for the elements including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure.

Da Silva et al. teach a stent including a dielectric part which mechanically connects but electrically insulates adjacent portions of the structure in order to enhance a signal (col. 7, lines 7-24). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a dielectric part which also insulates, as taught by Da Silva et al., to Leopold et al. in order to better enhance a signal.

Response to Arguments

10. Applicant's arguments filed 09/18/2009 have been fully considered but they are not persuasive.

11. Applicant argues that Leopold does not disclose a planar stent structure since the stents which may be flattened and stretched for placement within a guiding catheter are radially compressible (paragraph 76), but not necessarily planar. The examiner considers "planar" to mean flattened relative to an expanded condition, or having a level

surface. Since the stents of Leopold are made of a superelastic, deformable material (paragraph 45), they are capable of being completely flattened due to stress, including the cited embodiment shown in Figures 19-21, and then subsequently expandable into a 3-D structure when the stress is released, and therefore read on this claim limitation.

12. Applicant also argues that the side beams 126 are not continuous along a longitudinal axis, since they are interrupted from one section 132 to the next. However, the claims do not recite that the first and second spaced side beams extend continuously along the length of the structure, but rather along a longitudinal axis of the structure, and therefore any of the opposing first and second side beam sections 126 along the length of the structure in Figures 19-21 may be considered to be connected by a plurality of spaced cross-bands (specifically cross-bands 128 connect opposing first and second side beam sections 126).

13. Next, the applicant argues that Fischell et al. does not disclose a stent residing in a plane, or "disposed in a plane," as necessitated by claim 46. Such a description does not correspond to a structure that is planar or a structure completely residing in one plane (since even the applicant's structure has dimensions in all of the x, y, and z directions in conventional geometrical axes), but rather a structure that has dimensions in a plane. The stent of Fischell et al. therefore reads on this limitation because it is disposed in any of the x, y, or z planes.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734